To establish and maintain a *prima facie* case of obviousness under 35 U.S.C. § 103, M.P.E.P. § 706.02(j) states that, first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

It is respectfully submitted that there is no suggestion or motivation to combine the suggested references as asserted by the Office.

As is noted on page 4 of the Office Action, the prior art in Matsushima is relied on only because it allegedly teaches that "as the size of a peptide becomes shorter, its immunogenicity inside the human body decreases while also being more resistant to decomposition by proteases in the body, thus making it advantageous." (Office Action, pp. 4-5). However, page 36 of the instant specification shows that the applicants were not attempting to avoid the immunogenicity of the oligopeptide recited in independent claim 1. The specification identifies that "it is contemplated that a signaling molecule as provided herein finds an advantageous use as a co-stimulatory substance in a vaccine, accompanying modern day adjuvants or replacing the classically used myocobacterial adjuvants." (Specification, p. 36). As such, the instant specification discloses using an oligopeptide of at most 30 amino acids, as recited in claims 1-5, in combination with immunogenic adjuvants or as a replacement for the use of adjuvants.

Furthermore, the specification discloses the use of high molecular weight carriers for the single dose delivery of the oligopeptide recited in the claims 1-5. *Id.* at p. 23. Such high molecular weight carriers are often used to improve the immunogenicity of small peptides.

Therefore, because the specification discloses the use of immunogenic adjuvants and high molecular weight carriers during the delivery of the oligopeptide recited in claims 1-5, there would have been no motivation to combine Lunardi-Iskandar with Matsushima for the purposes of testing minimal length peptides with decreased immunogenicity and increased resistance to decomposition. The specification clearly states that the use of immunogenic compounds, such as adjuvants, was contemplated for the method of claims 1-5 and, as such, those of skill in the art at the time of the invention would not have been motivated to consider the teaching of Matsushima.

It is also submitted that Lunardi-Iskandar and Matsushima, alone or in combination, do

not teach or suggest all the elements of claim 1 or those claims dependent therefrom.

Claim 1 is directed towards a method for obtaining information about the capacity or tendency of an oligopeptide of at most 30 amino acids long to regulate expression of a gene comprising the steps of a) contacting the oligopeptide with at least one cell; and b) determining the presence of a NF-kappaB/Rel protein in or derived from the at least one cell. Thus, the oligopeptide is not more than 30 amino acids long.

Matsushima discloses a cell-free investigation of the effects of peptides of the I-kappaBalpha phosphorylation site on NF-kappaB activation.

Lunardi-Iskandar discloses four different forms of hCG which were contacted with tumor cells, all of which are greater than 30 amino acids long. The peptides used include:

1. Intact native hCG, which is 237 amino acids long
2. Native β-hCG, which is 145 amino acids long
3. A fragment of β-hCG, β-hCG$_{(109\text{-}145)}$, which is 36 amino acids long; and
4. Native α-hCG, which is 92 amino acids long.

(Lunardi-Iskandar, col. 10, lines 50-52).

The Office asserted without support that it would have been obvious to modify Lunardi-Iskandar and test β-hCG(109-119) because, allegedly "Lunardi-Iskandar et al teach that such small hCG fragments have activity." (Office Action, p. 5). However, Lunardi-Iskandar does not teach or suggest placing the β-hCG (109-119) in contact with at least one cell and determining the presence of a NF-kappaB/Rel protein in or derived from the at least one cell contacted with the β-hCG (109-119) as recited in claim 1.

Thus, Lunardi-Iskandar and Matsushima, alone or in combination, do not teach or suggest the method of determining the presence of a NF-kappaB/Rel protein in or derived from at least one cell contacted with the oligopeptide of at most 30 amino acids as recited in claim 1.

For the foregoing reasons, a *prima facie* case of obviousness has not been established for independent claim 1 and dependent claims 2-5. Accordingly, the withdrawal of the 35 U.S.C. 103(a) rejections of claims 1-5 is respectfully requested.

CONCLUSION

In view of the foregoing remarks, claims 1-5 should be in condition for allowance and an early notice thereof is requested. Should questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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Date: February 1, 2006